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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,534	11/28/2000	Merrill Goldenberg	A-576C	5310

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U.S. Patent Operations/ CAC
Dept. 4300, M/S 27-4-A
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/27/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,534	GOLDENBERG ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of GCSF as a species of biologically active agent in Paper No. 6 is acknowledged.

Claims 1-12 are under examination in the instant office action.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration, see Residence address of inventor Goldenberg. See 37 CFR 1.52(c).

Specification

3. The use of the trademarks has been noted in this application, see page 5, line 12 and page 15, line 16, for example. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is advised to review the entire text of the specification for other possible use of trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1 and 9 are vague and indefinite for the recitation of "polyol/thickened oil suspension" or "BAA/polyol/oil suspension". The metes and bounds of the recitation cannot be determined from the claims or the instant specification. It is not clear if the claims encompass suspension comprising polyol and thickened oil or polyol or thickened oil. Clarification is required.

6. Claim 7 is indefinite for the recitation of "interferon consensus". The recitation is confusing and ambiguous because it is not clear if the recitation encompasses any interferon or a mixture of different types of interferones.

7. Claims 8, 9 and 12 contain recitation of "BAA/polyol/oil". Applicant is advised that the terminology used should be consistent within the entire specification. If "oil" is intended to encompass "thickened oil", then this term should be used every time to avoid the confusion in interpretation of the claims. Clarification and appropriate correction is required.

8. Claims 2-6, 10 and 11 are indefinite for being dependent from indefinite claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-3 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Akerbloom, US Patent No. 5, 789,198.

Akerbloom describes a pharmaceutical composition in a form of suspension, which contains a polypeptide (see column 19, line 29-35), a polyol, sucrose or glycerol, and oil, such as sesame oil, with magnesium stearate or liquid paraffin (see column 20, lines 1-46). Thus, the disclosure of Akerbloom meets the limitations of claims 1-3 and 11.

Akerbloom further discloses a process of preparation of the pharmaceutical preparations by combining an active ingredient (a polypeptide) with solid excipient (a polyol sucrose) and further processing the mixture by adding suitable auxiliaries, such as oil (see column 19, lines 64-67 and column 20, lines 1-11). Thus, Akerbloom anticipates claims 8 and 12 of the instant specification.

Finally, the disclosure of Akerbloom encompasses pharmaceutical preparations for parenteral administration (see column 19, lines 43-48), which anticipates claim 9 and 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerbloom, US Patent No. 5,789,198, and further in view of Mitchell, US Patent No. 5,433,951, Ferguson et al., US Patent No. 4,977,140 and Sims et al. (J. American Oil Society, 1977, 54, 1, pp.4-7).

Akerbloom teach pharmaceutical composition comprising a biologically active agent, polyol, oil and binders, such as magnesium stearate, or stabilizers, see section of the instant office action. Akerbloom does not expressly disclose using aluminum stearate or white wax as ingredients, or adding methionine to the suspension.

Mitchell discloses prolonged release of composition comprising somatotropin, glycerol, an oil and aluminum monostearate (see column 6, lines 34-50 and column 7, especially lines 55-59). Mitchell also specifically discloses that "[c]ompositions of this invention are also useful for prolonged release of conjugated or unconjugated polypeptides [, such as] lipoproties, glycoproteins" etc. (see column 5, lines 62-68 and column 6, lines 1-4).

Ferguson et al. describes injectable sustained release formulation comprising somatotropin, wax and oil.

The effects of amino acids like cysteine and methionine on the rate of fat autoxidation are long and well known in the art. For example, Sims et al. describe addition of methionine to safflower oil to stabilize the oil to subsequent autoxidation.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included aluminum monostearate, a wax and methionine in the composition of Akerbloom for any biologically active agent, including cytokines and growth factors of claim 7 of the instant invention to produce a sustained release composition. One of ordinary skill in the art would have been motivated to do this because the reference of

Akerbloom clearly teaches the claimed composition with the exception of adding specific "thickener", such as wax or aluminum monostearate. Also, because the composition contains oils, it would be only obvious to add methionine as an antioxidant ingredient, which is appropriate for the use in compositions intended for clinical use. One of ordinary skill in the art readily recognizes that substitutions of these ingredients can be freely made, especially when advantages of such substitutions are well known and disclosed in the art (in this case in references of Mitchell and Ferguson et l.). Moreover, whereas the teachings of Akerbloom are limited to use of human leptin-receptor related protein and do not expressly reveal use of any polypeptide in the disclosed compositions, the disclosure of Mitchell et al. teaches compositions for prolonged release of somatotropin and other polypeptides, which encompasses any polypeptide, absent evidence to the contrary. Thus, claims 4-7 are obvious in view of this combination references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-12 are rejected under the judicially created doctrine of double patenting over claims 108 of U. S. Patent No. 6,245,740 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: claims 1-12 of the instant application are generic to, and fully encompass claimed subject of the '740 document.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent.

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
September 26, 2002 OC

JOHN ULM
PRIMARY EXAMINER
GROUP 1600